

Ontologies set the rules for describing such things and are therefore often explained as formal frameworks for representing knowledge. Many (200+) biomedical ontologies exist and a comprehensive repository can be found at the Bioportal (<http://bioportal.bioontology.org/>). The Radiation Oncology Ontology can be found at the Bioportal and a new ontology that tries to describe the radiation oncology domain.

Part of an ontology's formal definition is the assignment of a code or identifier to each entity. With the advent of Semantic Web technology and specifically the Web Ontology Language (OWL) these identifiers take the form of the web standard Uniform Resource Identifiers. As an example in the NCI Thesaurus, Intensity-Modulated Radiation Therapy has the URI

<http://ncicb.nci.nih.gov/xml/owl/EVS/Thesaurus.owl#C16135>.

When people use the same ontology and thus the same URI to code things, the datasets they generate are much more interoperable and can thus more easily be shared compared to using one's own terms and definitions to describe things. An ultimate goal of these efforts is to re-use clinical and research data in such a way that all radiation oncology becomes Linked Data, "a method of publishing structured data so that it can be interlinked and become more useful".

SP-0290

The issue of the quality of data in biobanking

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"Omics" approaches, particularly genomics, have been part of the drive towards the need for "big-data" to allow for meaningful analyses of the effects of complex factors and their interactions. To achieve such data in a timely manner has led to the establishment of an ever increasing number of scientific consortia that allow for the rapid pooling of both biological samples and their associated meta-data. Such consortia normally involve multiple individual smaller studies across several countries and often continents. This in turn raises challenges for the approach to biobanking and for the equitable sharing of the combined resource.

Two broad approaches to the biobanking have been adopted:

1. The individual study samples are sent and centrally pooled and analysed.
2. The samples are retained and analysed locally by the individual studies and the subsequent electronic data pooled. The first approach has the advantage of a more uniform approach to the analysis of the ensuing sample biobank but raises issues around appropriate documented material transfer arrangements. Such documentation is often not trivial and can run into difficulties in terms of the individual studies own legal and ethical restrictions on their wider use. It can also raise potential challenges to the storage and organisation of the samples to allow for subsequent efficient use in addition to issues around open and fair collaborative models of working that should allow for each contributing partner to have equitable access to the pooled resource.

The second approach raises a different set of issues in terms of ensuring quality and consistency of analyses of the samples

themselves across multiple labs and potentially different platforms. Furthermore, whilst allowing the individual studies seemingly greater retained "ownership" of the samples themselves the transfer of the ensuing data still raises the need for appropriate protocols for the ensuing controlled use of the pooled dataset itself.

Both approaches thus have their inherent limitations and both models continue to be used across different consortia. We will demonstrate some of the issues raised in practice using examples from our experience of involvement in large scale consortia in cancer. Particular issues around the time taken to achieve the appropriate paperwork for pooling raise important considerations for the planning of further initiatives whilst issues around equitable access give rise to potential feelings of unfairness and reduced willingness to participate in further consortia initiatives. Appropriate biobanking practices necessary for any subsequent re-sampling will also be considered. Such real and potentially imagined factors raise important issues going forwards with the "big data" agenda and could limit the most rapid and powerful integration of studies in the future.

In conclusion important lessons learnt from early consortia building initiatives, which have largely been built based on common sense principles, need to be learnt and integrated with more rigorous formal management standards such as ISO 9001, to maximise the utility and efficiency of large scale biobanks going forwards.

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The issue of multi-center comparison of imaging data

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Imaging data are increasingly used in radiotherapy. Functional imaging with FDG-PET is currently tested in several trials of dose painting. The versatility of MRI affords both anatomical and functional images: T2-weighted MRI provides anatomical detail with excellent soft-tissue contrast; diffusion-weighted MRI has potential as an early marker for response to treatment; dynamic contrast-enhanced MRI reflects the properties of the microvasculature in tissue. A clear connection with hypoxia has been established in cervical cancer and its prognostic value is also suggested in head and neck cancer. Increasingly, these imaging techniques are therefore added to clinical trial protocols to guide decisions about target delineation and dose levels, but also to monitor treatment response.

Traditionally, a qualitative interpretation of the data is given by the nuclear medicine physician or radiologist. This is sensitive to variations in imaging protocols influencing the appearance of the images. It also is subjective and relies strongly on observer experience. The use of quantitative, rather than qualitative data can be a solution to this problem. For PET, the Standard Uptake Value (SUV) has become the prevailing method to represent the data. Similar opportunities exist for MRI. T2-mapping combines anatomical information with quantitative information about the T2-value of the tissue. For diffusion-weighted imaging, the apparent diffusion coefficient (ADC) is a reproducible metric. For dynamic contrast-enhanced MRI, tracer kinetic modeling is used to extract quantitative data.

Quantification thus holds the prospect to provide data that are consistent between institutes and types of scanners. However, the advancement in understanding the value of imaging methods is held back by a lack of consistency in methodology. Different methods for acquisition and analysis

make comparison of results between different studies difficult and standardization is called for. The quantitative imaging biomarker alliance (QIBA) is an example of an initiative that aims to *improve the value and practicality of quantitative imaging biomarkers by reducing variability across devices, patients and time*.

Whereas standardization in methodology is important for quantification, it has to be able to accommodate emerging new techniques. It is untenable to continue using outdated methods, simply because earlier studies did not have access to more advanced equipment. Therefore, within a multicenter project using quantitative MRI for imaging cancer in the prostate and cervix, we developed a procedure that allows each center to use the optimal sequences for their scanner. In a series of phantom and volunteer experiments these sequences are benchmarked against well-established sequences which are robust, but typically too slow for clinical use. Consistent quantification with a bias of a few percent between different scanners and institutes was feasible for T2 mapping, as well as for diffusion-weighted MRI. With newer scanners and sequences typically more precise results were obtained. This strategy is therefore a way to achieve consistency between quantitative results from different centers and studies.

SP-0292

The issue of the quality of data in clinical trials

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Clinical trials are considered as the most rigorous way to prospectively evaluate the efficacy and toxicity of treatments. When randomized designs are used they also provide comparative effectiveness between several therapies. Good Clinical Practice is the universal ethical and scientific quality standard for conducting clinical trials and applies to all aspects of the clinical trial process. Quality is viewed as a continuum, going from trial design to analysis and reporting. The quality of a clinical trial at an investigator site is usually assessed by sponsor audits and regulatory inspections, but radiation oncology trials can, through RTQA procedures, include an innovative means of quality assessment which can ultimately generate data and hypotheses. The Clinical Trials Transformation Initiative has defined quality as “the ability to effectively answer the intended question about the benefits and risks of a medical product (therapeutic or diagnostic) or procedure, while assuring protection of human subjects”.

The different issues of quality in clinical trials will be discussed, including trial design, statistical hypotheses, interventions, data recording and monitoring, statistical analysis, trial reporting and interpretation. Means to improve trials quality and generalization of trials' results will also be discussed. All the limitations to data quality in prospective trials described will also apply to other forms of clinical research, such as data-mining, and are usually minimized and controlled in randomized trials. It is crucial to allow external audit and meta-analyses, as these procedures can identify and potentially reduce biases. Ultimately the reader is the last judge of trial quality through the critical reading of medical literature.

Symposium: Risk management: QA and safety 1

SP-0293

The ESTRO task force on risk management - A Status Report

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Aim: ESTRO has formed a task force on risk management within radiation oncology (RO). ESTRO represents all the professionals working within RO and is therefore the most appropriate partner to work with on issues relating to risk and risk management within radiotherapy. One example is in the implementation of the latest EU directive on basic safety standard in radiation protection, which will make reporting and learning from incidents and near incidents a legal requirement. ESTRO works closely with the National Societies in EU and is ideally positioned to inform and advise on this and all other related issues.

Methods: The remit of the working group was to define the specific tasks that should be carried out. These include:

- To develop a body of knowledge in order to position ESTRO such that they can inform and influence policy with respect to risk management in radiotherapy at the level, for instance of the European Commission
- To prepare and disseminate information to the National Societies and the ESTRO community on important developments in the area of risk management and incident reporting and learning that they should be aware of.
- To position ESTRO as an interface with other professional bodies such as ASTRO/AAPM to ensure consistency of approach internationally.
- To liaise between European and global bodies, the National Societies and the ESTRO community to advise with respect to effective implementation of the new EURATOM Directive.
- To carry out a scoping exercise of all the current activities in the area of risk management and incident learning specifically to identify variations and inconsistencies.

- Incident Learning Systems (ILS):
 - • ROSIS, SAFRON (IAEA)
 - • RO-ILS (ASTRO/AAPM)
 - • National Reporting and Learning System - NRLS with specific coding for RT (UK)
 - • Canadian Partnership for Quality in Radiotherapy - CPQR (Ca)
 - • Etc...

Consistent with the requirements of the new EURATOM Basic Safety Standards which will mandate new measures in relation to risk management in radiotherapy, the ESTRO, as the European professional body in radiotherapy should be in a position to give direction in relation to (for example):

What should be considered a mandatory reportable event
Carrying out prospective analysis when new technology is introduced